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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,848	01/11/2002	Ram Dutta Pathak	P30835DIV2C2	9105

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GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/044,848	Applicant(s) PATHAK ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17, 18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Extension of Time, the Amendment C, the Information Disclosure Statement, and the Supplemental Prior Art with Attachment, received by the Office November 13, 2002, December 9, 2002, December 9, 2002, and March 3, 2003, respectively.

Information Disclosure Statement

The information in the information disclosure statement has been considered, per Applicant's request. The information available as prior art has been cited, acknowledged, and made of record. The remaining information on the information disclosure statement (the Civil Actions) have been considered but are not deemed relevant because they are not prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,721,723 to Barnes *et al* (hereinafter Barnes). Barnes discloses crystalline paroxetine hydrochloride hemihydrate, processes for its preparation, compositions containing it, and its therapeutic use as an anti-depressant (abstract). Barnes teaches that the drug is usually adapted for oral administration, such as tablet form (c 5, l 49-60). Additionally, Barnes teaches that the unit

dosage form usually contains from 1 to 200 mg of the active ingredient (c 5, l 53-55). Barnes also teaches that suitable carriers may be included. Further, Barnes teaches that the composition can be formulated by conventional methods of admixture such as blending, filing, and compressing.

Claims 16-19 are rejected as product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Barnes also teaches that the active ingredient is used for the treatment of depression. Therefore, Barnes anticipates the generic claims to a composition comprising Paroxetine and excipients.

Applicant's arguments have been fully considered but are not found to be persuasive. First, Applicant argues that product by process claims are not per se anticipated by a generic disclosure. Applicant reasserts that the Examiner cannot ignore the characteristics or properties that are imparted to the product by the process recited in the claims. Applicant further contends that the characteristics and properties imparted to the claims product by the claimed product renders the instant invention patentable over the cited reference. The examiner respectfully disagrees. As discussed in the interview, process limitations in a product claim only have patentable weight if they cause a different product to be made, and said differences in the

product are included in the claim limitations. As currently claimed, the only patentable limitation in Applicant's claims is a tablet containing paroxetine. The process limitations do not render weight to the claim. Applicant can either claim the product, including any components which are different than the prior art, or Applicant can claim a process. However, the instant limitations drawn to a process do not make the product patentable, because there are no limitations in the claim directed to differences between the prior art product and Applicant's product.

Applicants further recite that a claim cannot be anticipated unless each and every element as set forth in the claim is found in a single prior art reference. However, as discussed in the MPEP passage recited above, product by process claims are examined differently, and to anticipate it is only necessary to meet all the product limitations.

Applicant has also submitted declarations in an attempt to overcome the rejection over Barnes *et al.*. However, these declarations are found to be unpersuasive. First, the declaration of Dr. Doughty states that pharmaceutical tablets can be formulated by wet or dry methods, and that each of these methods can impart different physical characteristics to the final tablet. This statement affirms the examiner's position that the Barnes formulation may have been made using dry granulation, particularly because, as Applicant admits, both wet and dry granulation techniques are known in the art. Additionally, based on Applicant's instant claims, it is insignificant that the two processes can impart different characteristics to the product, because the claims do not recite these differences. Dr. Doughty also declares that commercial scale formulations of paroxetine prepared in the absence of water are less likely to develop of pink hue. This is unpersuasive for two reasons. First, as stated above, the process limitations are not

considered in a product claim. Second, the only product difference that has been discussed by Applicant is the presence or absence of a pink hue. Currently, this is not found to render patentable weight because it is not a claim limitation. However, even if it were present in the claim language, this statement by Applicant would make it unpersuasive, because Applicant himself is admitting that their formulation *can* develop a pink hue. (Applicant states "less likely to develop a pink hue.")

The Affidavits of Drs. Rhodes and Roman again discuss the improvements realized by changing the wet granulation tablet formulation to dry admixing and compressing process. As stated repeatedly above, the instant claims are drawn to products, not processes, and therefore, this argument is moot. Additionally, Drs. Rhodes and Roman admit that the pink hue did not appear in every batch using wet granulation. This reiterates the examiner's above point, that using wet granulation or drug granulation, the formulation may develop a pink hue. (Dr. Doughty declared that the pink hue has only been made less likely, it has not completely disappeared, and Drs. Rhodes and Roman admit that the pink hue did not appear all the time using wet granulation). Applicant has stated that the major improvement in their invention revolves around the alleged pink hue of the prior art, however, it appears that this pink hue can still appear. It is therefore unclear what the claimed improvement is.

Furthermore, the declarations and affidavits continuously discuss the prior art as though it clearly stated that the products were made using wet granulation. As stated before, this is clearly not the case. There has been no evidence provided to show that Barnes used wet granulation. Applicant asserts that the examiner can not rely on Barnes because the reference teaches no

processes. Again, this is insignificant, because the claims are drawn to compositions, not processes.

The examiner's again discuss that many of the statements in the declarations and affidavits submitted are found to be speculations and personal opinions of the declarants, and these statements lack the scientific evidence and data to make them persuasive. For example., Dr. Rhodes states that if a drug formulator were to make tablets based on the disclosure in Barnes, at the time the Barnes patent application was filed, the tablets would be wet granulated because that was the conventional process at that time. There is absolutely no evidence to back up this assertion. The examiner cites Remington's Pharmaceutical Sciences as a reference of interest. The 1990 addition (just two years after the Barnes patent was issued) discloses that well known method of tablet formulation include wet and dry granulation. Barnes doesn't teach the use of either wet or dry granulation, because both were well known at that time.

Lastly, Applicant's discuss the reason the pink hue is detrimental. These reasons are not found persuasive because this limitation is not found in the claim. Therefore, the arguments are not commensurate in scope with the instant claims.

Claims 16 –19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/09281 to Johnson. Johnson discloses the use of paroxetine or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for use in the treatment of senile dementia (abstract). Johnson further teaches that an acceptable salt of paroxetine is paroxetine hydrochloride (p 1, l 34-35). Johnson also teaches that the medicament can be in tablet form for oral administration (p 2, l 29), and may include excipients suitable for oral administration, such as calcium phosphate,

magnesium stearate, and sodium starch glycolate (p 3, l 1-8). Johnson also teaches that the formulation will generally contain between 2 and 1000 mg, more preferably between 30 and 500 mg per dosage form (p 4, l 32-35). Lastly, Johnson teaches that the formulation may be obtained by conventional methods of blending, filling, tabletting, or the like (p 3, l 12-13).

Claims 16 –19 are rejected as product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Furthermore, Johnson anticipates the limitations of the composition claims, as he discloses a pharmaceutical tablet comprising paroxetine hydrochloride and excipients.

Applicant's arguments have been fully considered but are not found to be persuasive. The arguments regarding this rejection are similar to the ones regarding the Barnes rejection, and therefore no additional response to those arguments is deemed necessary. However, the examiner restates the following response to earlier arguments.

Previously, applicant argued that the processes used to produce the paroxetine tablets sold at the time of the instant invention were formulated using an aqueous granulation process, which results in an unacceptable formulation in that a highly undesirable pink hue was formed on the tablet. However, applicant has provided no support for this comment. Additionally, Applicants argued that Johnson does not discuss the problem or solution focused on by applicant.

These arguments are not found to be persuasive for three reasons. First, there is no evidence that the product disclosed by Johnson possesses the pink hue as suggested by applicant. Second, even if the Johnson formulation does contain the pink hue, there is nothing in the claim language to state that the formulation can not have a pink hue. Third, applicant is claiming a composition, not a method of making a composition. As discussed in the original, and above rejections, even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself.

Claims 16 –19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 269 303 to Lassen. Lassen discloses a method for treating pain which comprises administering an effective amount of paroxetine or an acceptable salt thereof (abstract). Lassen further teaches that an acceptable salt of paroxetine is paroxetine hydrochloride (p 2, l 14). Lassen also teaches that the medicament can be in tablet form for oral administration (p 2, l 33-36), and may include excipients suitable for oral administration, such as calcium phosphate, magnesium stearate, and sodium starch glycolate (p 2, l 39-44). Lassen also teaches that the formulation will generally contain between 2 and 1000 mg, more preferably between 30 and 500 mg per dosage form (p 3, l 17-20). Lastly, Lassen teaches that the formulation may be obtained by conventional methods of blending, filling, tabletting, or the like (p 2, l 45-46).

Claims 16 –19 are rejected as product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the

same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Furthermore, Lassen anticipates the limitations of the composition claims, as he discloses a pharmaceutical tablet comprising paroxetine hydrochloride with excipients.

Applicant's arguments have been fully considered but are not found to be persuasive. The arguments regarding this rejection are similar to the ones regarding the Barnes rejection, and therefore no additional response to those arguments is deemed necessary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 –19 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 269 303 to Lassen or WO 92/09281 to Johnson or US Patent 4,721,723 to Barnes *et al.* as applied to claims 16 –19 above. Neither Lassen nor Johnson gives a specific example teaching applicant's exact method. However, as stated above, the claims are rejected as product by process claims, because Johnson and Lassen both teach applicant's claimed product. Furthermore, both references teach that the oral tablet may be formulated by any conventional method. One of ordinary skill in the art would have been motivated to create an oral formulation comprising paroxetine and the instantly claimed excipients, based on the teachings of Johnson and Lassen.

The expected result would be a successful pharmaceutical formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Lastly, as is stated in applicant's declaration, both wet and dry granulation methods are well known methods for tablet formulation. Furthermore, there has been no evidence provided to persuade the Office that the prior art cited used one method of tableting over another. However, the prior art does not discuss the commercial scale limitation of applicant's claims. However, in *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976), it was determined that "mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.) See MPEP 2144.04 IV.

Applicant's arguments have been fully considered but are not found to be persuasive. The arguments regarding this rejection are similar to the ones regarding the Barnes rejection, and therefore no additional response to those arguments is deemed necessary

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Tech Center 1600/ AU 1615
March 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600